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10/574,331	03/31/2006	Seok Soo Kim	930086-2025	5885

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EXAMINER

BLAND, LAYLA D

ART UNIT	PAPER NUMBER
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1623

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,331	Applicant(s) KIM ET AL.	
	Examiner LAYLA BLAND	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is a response to Applicants' amendment submitted April 22, 2009, wherein claims 2, 5, and 6 are amended and claims 13-17 are newly submitted. Claims 1-17 are pending. Claims 8-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 20, 2008. Claims 1-6 and 13-17 are examined on the merits herein.

The following new or modified rejections were necessitated by Applicant's amendment submitted April 22, 2009, wherein a cooling step was added to claim 2 and wherein new claims 13-17, containing new limitations to purity, amount of alkyl halide added in the first step, and total amounts of methyl chloride compared to total amounts of sodium hydroxide were added.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. Newly submitted claim 17 recites the limitation

"total amount methyl chloride added through the first and second reactions is less than the total amount of sodium hydroxide added through the first and second reactions."

Applicant states that claim 17 is supported by the Examples in the specification.

However, all of the Examples in the specification (Example 1 and Table 1), are drawn to processes which use more methyl chloride by weight than sodium hydroxide. It is noted that the caustic soda used in the examples was a 50 wt% solution (see Example 1), so the amounts in Table 1 should be approximately halved to arrive at the amount of sodium hydroxide added. Thus, new claim 17 is not supported by the specification.

This is a new matter rejection.

The following rejections are maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 6, and 13-17 recite the limitation "efficiency of substitution by alkylene oxide" or "efficiency of substitution by alkyl halide." It is unclear how the efficiency is determined or what the term is intended to mean. The specification, pages 10-11, states that efficiency was determined by "calculating the proportion of substitution." In

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Table 2, Example 1, the degree of methoxyl substitution is 28.5 and the degree of hydroxypropoxyl substitution is 6.5; the methyl chloride efficiency is 61.2% and the propylene oxide efficiency is 62.5%. It is unclear which values were used to arrive at the efficiency numbers. Furthermore, the specification, page 5, states that the maximum value for degree of substitution is 3 but the degree of substitution given in Table 2 is much higher than 3.

Claims 5 and 6 are drawn to the method of claim 1, wherein the efficiency of substitution of alkylene oxide is 60-75%, or wherein the efficiency of substitution of alkyl halide is 60-70%, respectively. Claim 14 ultimately depends from claim 1 and recites the limitation "purity with an amount of water insoluble ingredients of less than 0.02 wt%." The method of claim 1 is quite broad, including no limitations on temperature or time, and including very broad ranges for amount of reagent used (5-80%, 0.5-4 moles). It is unclear which conditions within claim 1 will result in an efficiency of alkylene oxide of 60-75%, or an efficiency of alkyl halide of 60-70%, or the recited purity. MPEP 2173 states: "The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent." The skilled artisan would not know if he or she was infringing because the conditions required for achieving the recited efficiencies are not set forth.

Response to Arguments

Applicant argues that amended claims 5 and 6 refer to efficiency as related to degree of substitution, which is a well known measurement. As set forth above, it is

unclear how degree of substitution is related to efficiency. It is noted that Applicant did not address the rejection with respect to which particular conditions are required to achieve the recited efficiencies.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3-6, 13, 14, and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Kim (KR 10-2003-0092006, published June 22, 2005, machine translation, of record).

Kim teaches a method for preparation of hydroxyalkylalkylcellulose, wherein 4.5 kg of 50% sodium hydroxide is added to 7 kg of pulp, and then 6.0 kg of methyl chloride and 4.0 kg propylene oxide and the mixture reacted for 1 hour at 80°C. Then 5 kg of a second sodium hydroxide solution were injected, followed by 7.0 kg of methyl chloride and the mixture was further reacted at 90°C for 1 hour. [page 5, Embodiment 1].

Generally, the first alkali metal hydroxide is used at about 0.5-4.0 molar ratio. The first methyl chloride should be used at about 0.5-3.0 molar ratio compared to the cellulose. The alkylene oxide should be used at about 1.0-2.5 molar ratio. The second sodium hydroxide should be used at about 1.0-4.0 molar ratio, and the second alkyl halide at about 2-6 molar ratio. [page 4, second paragraph - page 5, first paragraph]. Kim's

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method steps are the same as the instant method steps, and thus the claims are anticipated.

Response to Arguments

Applicant argues that, after the first alkali metal hydroxide addition step in Kim, the entire quantity of alkylene oxide is added and the entire quantity of alkyl halide is added after the second alkali metal hydroxide addition. Applicant refers to claim 1 of the English translation and comments in the instant specification. This argument is not persuasive because Example 1 of Kim clearly teaches two steps, and sodium hydroxide and methyl chloride are added in each of them. Kim's claim 1 and the remarks in the instant specification were not relied upon for the rejection and do not nullify the teachings in Example 1. Thus, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-6, 13, 14, and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dannhorn et al. (US 2003/0065165, April 3, 2003, of record).

Dannhorn et al. teach a process for preparing methyl hydroxypropyl cellulose wherein cotton linters were reacted with 1.57 eq. of chloromethane, 2.0 eq. of sodium

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hydroxide, and 0.8 eq. of propylene oxide at 85°C. After reaction at 85°C for 120 minutes, 1.2 eq. of sodium hydroxide and 3.36 eq. of chloromethane were metered in and the mixture reacted at 85°C for another 120 minutes. [Example 12, paragraph 0061 and Table 2]. The total amount of chloromethane added was 4.93 eq. (1.57 + 3.36). Thus, the first portion was about 32% of the total and the second portion was about 68% of the total. Dannhorn's method steps are the same as the instant method steps, and thus the claims are anticipated.

Dannhorn et al. do not specifically mention "agitating" or "dispersing" the mixture between addition of reagents. However, it appears that the mixture was stirred throughout the process; "while stirring," "stirred for 120 minutes," "stirred for another 60 minutes," etc., which is considered the same as agitating or dispersing. Example 12 does not specifically mention the order of addition in the last phase of the reaction; whether sodium hydroxide or chloromethane was added first. However, Dannhorn et al. teach that the second portion of methyl chloride can be added before, during, or after the addition of the second portion of sodium hydroxide [0052], so it would have been obvious to do so.

Response to Arguments

Applicant argues that Dannhorn's process has only one reaction step. This argument is not persuasive because paragraph [0061] clearly states that there are two separate additions of methyl chloride and sodium hydroxide. Thus there are two reaction steps.

Applicant argues that Dannhorn's process takes place in a different sequence. Applicant did not specify where the sequence differs, and it is unclear to the Examiner. As set forth above, Dannhorn teaches that the second portion of methyl chloride can be added before, during, or after the addition of the second portion of sodium hydroxide. Thus, Applicant's argument is not persuasive.

Applicant argues that Dannhorn's process takes longer than the instant process. This argument is not persuasive because the instant claims are not limited to any reaction time. See MPEP 716.02(d): Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing the unexpected results must be reviewed to see if the results occur over the entire claimed range.

Applicant argues that Dannhorn uses a greater number of equivalents of alkylating agents compared to alkali, unlike the claimed process. This argument is not persuasive because, as set forth above, Applicant's caustic solution is only 50% by weight NaOH (and thus the calculation on page 10 of Applicant's response is incorrect), and Dannhorn's teachings encompass ratios of reagents which include larger amounts of NaOH than MCL.

Applicant argues that Dannhorn's examples show a greater degree of variability in methoxyl substitution than the examples in the instant specification. This argument is not persuasive because Dannhorn's examples included different amounts of

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reagents. Thus, the degree of methoxyl substitution would be expected to be different in each example.

Applicant argues that Dannhorn's examples show sedimentation. This argument is not persuasive because Dannhorn teaches sediment only in Examples, 22, 27, and 28. The vast majority of Dannhorn's examples, including those relied upon in the rejection, did not show sedimentation. Furthermore, as set forth above, Applicant's process is very broad and it is unclear which conditions are required to achieve the claimed purity. See MPEP 716.01(b): "To be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations." Because the claims are broad and there is no indication of which conditions within the broad claims result in the claimed purity, there is no nexus between the merits of the claimed invention and evidence of secondary considerations.

For these reasons, the rejection is maintained.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (KR 10-2003-0092006, published June 22, 2005, machine translation, of record) or over Dannhorn et al. (US 2003/0065165, April 3, 2003, of record) in view of Adams (US 4,661,589, April 28, 1987, PTO-1449 submitted March 31, 2006).

Kim or Dannhorn teach as set forth above, but do not teach a cooling step.

Adams teaches a 2-stage process for preparing hydroxyalkylalkylcellulose ethers which is carried out at elevated temperatures, and the reaction mass can be cool for the addition of incremental amount of caustic [column 5, lines 35-38].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to carry out Kim's or Dannhorn's process, and to employ a cooling step between the two stages. Adams teaches that similar process which can include a cooling step, and thus the skilled artisan would expect that the cooling step could be successfully employed in Kim's or Dannhorn's process.

Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim (KR 10-2003-0092006, published June 22, 2005, machine translation, of record).

Kim teaches as set forth above, but does not exemplify a process wherein the total amount of methyl chloride is less than the total amount of sodium hydroxide, and does not exemplify a process wherein the amount of alkyl halide in the first step is 50-90 wt% of the total. However, Kim teaches that the total amount of alkali metal hydroxide which can be used is 1.5-8.0, and the total amount of methyl chloride which can be used is 2.5-9. Thus, Kim's teachings encompass reactions wherein the total amount of methyl chloride is much less than the total amount of sodium hydroxide. Kim also teaches that the first alkali metal hydroxide is used at about 0.5-4.0 molar ratio, and the second alkyl halide at about 2-6 molar ratio. Thus, Kim's teachings encompass

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reactions wherein the first amount of methyl chloride is 50-90% of the total. The skilled artisan, using Kim's teachings, could arrive at the claimed invention using no more than routine experimentation.

Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dannhorn et al. (US 2003/0065165, April 3, 2003, of record)

Dannhorn teaches as set forth above, but does not exemplify a process wherein the total amount of methyl chloride is less than the total amount of sodium hydroxide and does not exemplify a process wherein the amount of alkyl halide in the first step is 50-90 wt% of the total . However, Dannhorn teaches that the preferred amount of MCL in the first step is minimum 1 eq of NaOH - 1.4 and maximum eq of MCL is 1 eq of NaOH plus 6.5 [0048]. In the second stage, the minimum eq of NaOH is 0.2-1.5; the minimum eq of MCL is 1 eq NaOH minus eq of MCL I, preferably 0 to 2.5 eq. Thus, Dannhorn's teachings encompass the claimed ratios of MCL and NaOH and the claimed ratio of first/second addition of MCL. The skilled artisan, using Dannhorn's teachings, could arrive at the claimed invention using no more than routine experimentation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623